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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,125	10/04/2004	Shalaby W. Shalaby	SHA-38-PCT-US	6610
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LEIGH P. GREGORY PO BOX 168 CLEMSON, SC 29633-0168			EXAMINER DICKINSON, PAUL W	
			ART UNIT	PAPER NUMBER
			1618	
			MAIL DATE	DELIVERY MODE
			01/07/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/510,125

**Applicant(s)**

SHALABY, SHALABY W.

**Examiner**

PAUL DICKINSON

**Art Unit**

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date: \_\_\_\_\_

### **DETAILED ACTION**

Applicant's arguments, filed 9/29/2008, have been fully considered but they are not deemed to be fully persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objects are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

#### ***Response to Arguments***

##### ***Claim Rejections - 35 USC § 102 and 103***

The rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by EP '171 (EP 0952171) is maintained. The rejection of claims 1, 4, 11-12, and 14 under 35 U.S.C. 103(a) as being unpatentable over EP '171 is maintained. The rejection of claims 1, 3-4, and 9-16 under 35 U.S.C. 103(a) as being unpatentable over EP '171 in view of '893 (US 20020041893) is maintained. The rejection of claims 1-4 and 9-16 under 35 U.S.C. 103(a) as being unpatentable over EP '171 in view of '893 in further view of '747 (US 5149747) is maintained.

The rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by WO '908 (WO 9921908) is maintained. The rejection of claims 1, 4-8, and 17-18 under 35 U.S.C. 103(a) as being unpatentable over WO '908 is maintained.

Applicant's arguments center on EP '171 and WO '908. Regarding EP '171, Applicant argues that EP '171 is directed to liquid copolymers. Regarding WO '908, Applicant argues that the composition of WO '908 is a liquid, otherwise it would not be

injectable. One of ordinary skill in the art would recognize that liquid polymers could not be used as necessarily solid coatings for endovascular stents.

Applicant's arguments have been fully considered but are not found persuasive.

Regarding EP '171, no where does the reference require the copolymer to be in the liquid state, rather, the reference is directed to hydrogel-forming, self-solvating, absorbable polyester copolymers which form hydrogels upon contact with water (see abstract). Hydrogels are fully capable of acting as stent coatings. For further support, the Examiner cites US 20020091433, which teaches that hydrogels are fully capable of acting as stent coatings (see paragraph 7). For the sake of argument, if the composition of EP '171 were restricted to liquid polymers, such liquid polymers are also known in the art to serve as stent coatings. For support, the Examiner cites US 20030083740, which teaches liquid polymer stent coatings (see paragraph 89).

Regarding WO '908, the reference explicitly states that the polymers may be in solid form (see abstract). Again, for the sake of arguments, if WO '908 were limited to liquid polymers, such liquid polymers could serve as stent coatings.

### ***New Grounds of Rejection***

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP '171 (EP 0952171; document already in record) in view of '256 (US 6124256).

EP '171 discloses polyester copolymers and their utility in providing a protective barrier to prevent post-surgical adhesion, treatment of defects in conduits such as blood vessels, and controlled release of a biologically active agent for modulating cellular events such as wound healing and tissue regeneration (see abstract; ¶ 22-34). Triblock copolymers comprising a central polyoxyethylene segment and a terminal polyester segment formed from glyclide, lactide, and epsilon-caprolactone (cyclic monomers) are

disclosed (see ¶¶ 53-57). Di-lactide/glycolide is exemplified (see Example I). The end groups can optionally be carboxylated by an acylation with an appropriate agent, such as succinic anhydride (see ¶¶ 54). The bioactive compounds to be incorporated include non-steroidal anti-inflammatory agents such as naproxen and anti-cancer drugs such as somatostatin analogs (antiangiogenic peptides), and mixtures thereof (see ¶¶ 57 and 66). The reference discloses that a combination of two or more drugs may be necessary for optimal effectiveness (see ¶¶ 66). The polymers may have one or more ionically bound bioactive peptides or a proteins, such as naproxen (see ¶¶ 46, 32, and 84; Example XV).

The phrase "stent coating composition" is an intended use. A recitation of an intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, the composition disclosed by EP '171 is fully capable of being used as a stent coating.

EP '171 fails to teach incorporation of lanreotide into the composition.

'256 discloses that lanreotide is a somatostatin analog and exerts a number of vascular effects such as inhibition of angiogenesis and prevention of dysplastic lesion formation (see col 1, line 13 to col 2, line 37; "Other Publications").

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to incorporate lanreotide, a somatostatin analog, into the formulation of EP '171 to optimize the vasculoprotective effect of the composition. The expectation of success is high, as EP '171 teaches incorporation of somatostatin

analogs and '256 teaches that lanreotide provides inhibition of angiogenesis and prevention of dysplastic lesion formation.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/  
Supervisory Patent Examiner, Art Unit 1618

Paul Dickinson  
Examiner  
AU 1618

December 29, 2008